Pandemic profiteering and refusal to share vaccines equitably

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Talk outline

- Exorbitant pharmaceutical profits despite public funding.
- Inequitable vaccine distribution.
- Australia's response.
- Discussion: should we forego vaccine boosters?
- Failure of current schemes to address inequality.
- The underlying problem: TRIPS, IP and patents rights.
- Australian medicines policy: equitable access.
- Discussion: waive IP protection on Covid-19 technologies?
- Is progress possible?
  - Salk polio vaccine.
- Discussion: vaccine passports?

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WHO is calling for a moratorium on COVID-19 vaccine boosters

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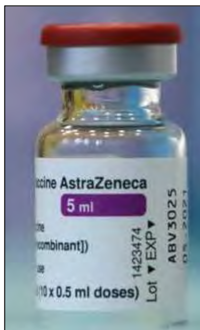
Exorbitant pharmaceutical profits despite public funding



- Governments have directly contributed $12 billion plus of public money for vaccine discovery and expanded manufacturing. They have also entered into $24 billion of advance purchases agreements.
- However, Pfizer has recently increased the price-per-dose of its COVID-19 vaccine by 24% to just over AUD $31.
- Moderna has also increased the price of its mRNA vaccines in Europe to AUD $41 per dose.
- In contrast, AstraZeneca is providing its Covid vaccine not for profit at around AUD $4 until the pandemic is over.

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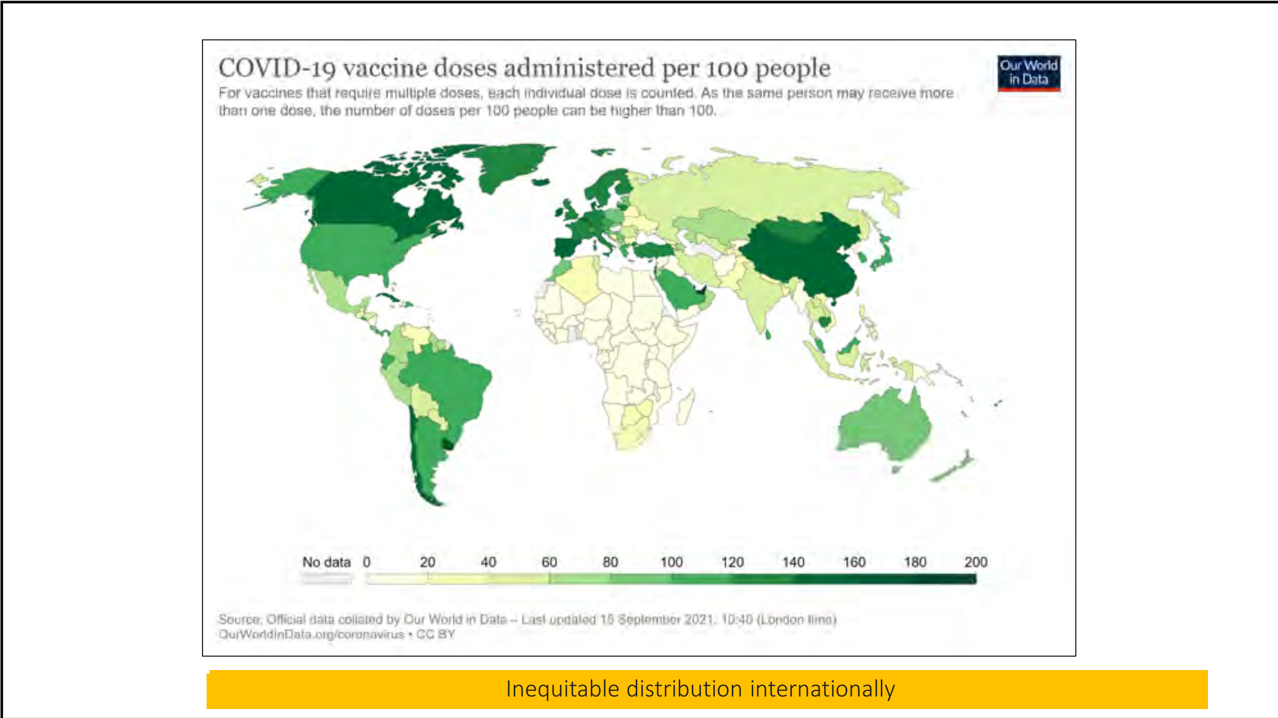

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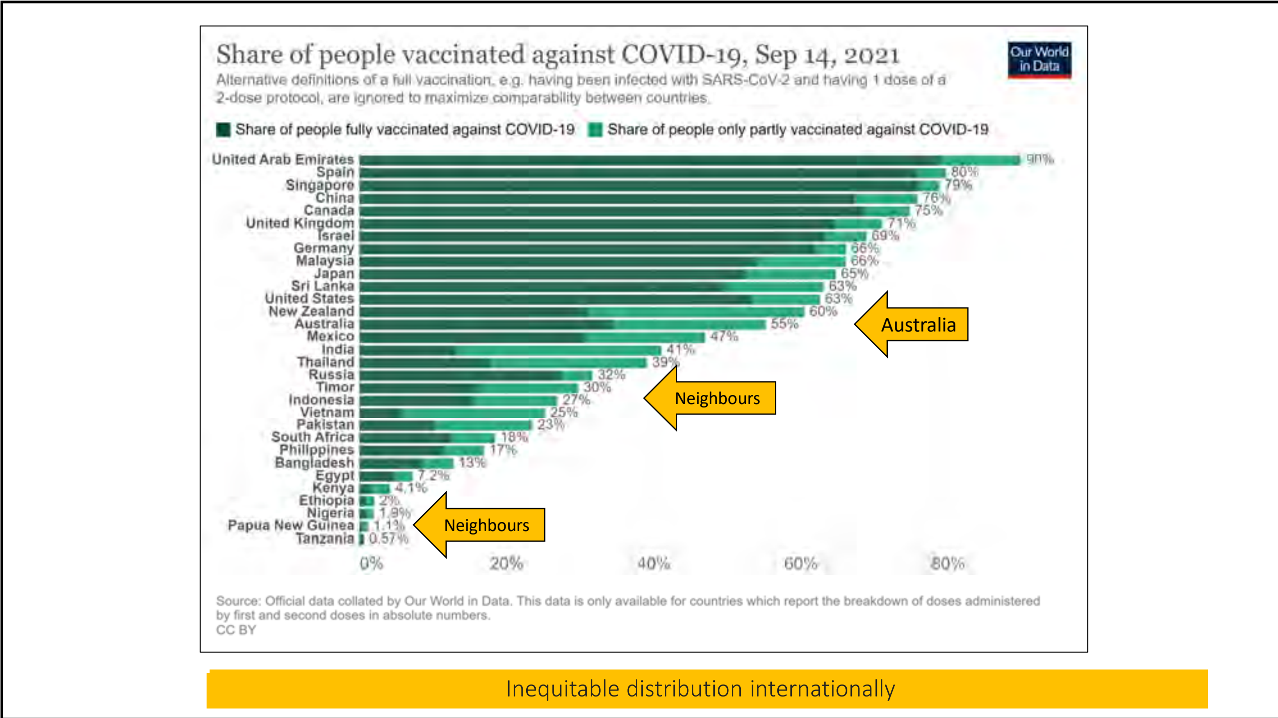

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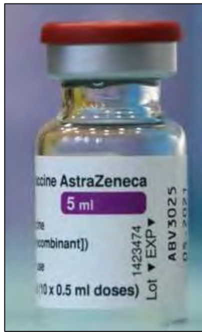
Australian vaccine purchases



Vaccine	Purchases
AstraZeneca	50 million from CSL, plus 3.8 million from offshore
Pfizer	40 million in 2020-21, plus 1 million from Poland, plus 85 million for boosters in 2022-23
Moderna	10 million in 2021, plus 15 million boosters in 2022
Novavax	51 million (when approved by TGA)

TOTAL: 256 million doses for our 25 million population.

That's enough doses to vaccinate all our citizens with two doses and a booster, three times over.

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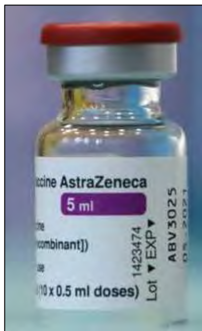
Australian vaccine donations



Country	Commitment
Vietnam	0.4 million AZ as 1st instalment of 1.5 million doses.
Indonesia	0.5 million AZ as 1st instalment of 2.5 million doses.
Papua New Guinea, East Timor and Pacific Islands	Pledged to share up to 15 million vaccine doses with Pacific nations and East Timor by mid-2022. Several million AZ jabs have already been distributed.

TOTAL: 19 million doses shared; 256 million doses for us.

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Other commitments

- **Vietnam:** $40 million package of vaccine-related support including providing funding for syringes, training of healthcare workers, fridges to maintain cold chain storage, and support for the vaccine rollout in remote provinces.
- **Indonesia:** $101.9 million to support Indonesia's national vaccine rollout through the $523 million regional Vaccine Access and Health Security Initiative plus 1000 ventilators, 700 oxygen concentrators and 20,000 rapid antigen tests already delivered.
- **Quad Vaccine Partnership** with the United States, Japan and India, $100 million commitment.
- **COVAX** Advance Market Commitment, contribution of $130 million to the providing fair and equitable access to vaccines in developing nations. Since March this year, COVAX has provided more than 19 million doses to Indonesia.

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Vaccine diplomacy?

- Sinopharm is said to be a key component of China's "vaccine diplomacy", where hundreds of millions of doses of Chinese-made vaccines are being offered to low- and middle-income countries around the world.
- In the same week Sinopharm was launched in the Pacific, Australia pledged to donate tens of thousands of additional doses of its AstraZeneca jabs to Pacific nations, in what some say points to a growing diplomatic rivalry between China and Australia in the region.
- China has accused Australia of using vaccines to push for political influence in the region.

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Australia's Foreign Aid

Ratio of development assistance compared to gross national income

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Discussion: should we forego vaccine boosters?

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Failure of current schemes to address inequality: Covax

- COVAX, formally known as the COVID-19 Vaccines Global Access Facility, is a global collaboration aimed at speeding up the development, manufacture and equitable distribution of new vaccines. It is a partnership between WHO, Gavi, CEPI and UNICEF.
- COVAX facilitates participants' buying power by getting vaccine manufacturers to produce the vaccines at scale and make risky early investments in manufacturing capacity.
- It was hoped to buy enough doses to vaccinate at least 20% of people in 92 poorer countries by the end of 2021. It's way off target. Rich nations pushed COVAX to the back of the queue of buyers, and it has struggled with procurement, delivering just 163 million doses, far short of the billions needed. Disappointingly, the G7 agreed to donate less than 8% of the required doses to COVAX.
- In addition, the U.S. renounced COVAX, and France and Germany, though officially part of the global collaboration, have already made deals with pharmaceutical companies to secure vaccines for their populations and will not purchase them through the international effort.
- Critics are also concerned COVAX does not require vaccines be made available at cost and has not secured open access licenses that would allow knowledge sharing and distribution sector.

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Failure of current schemes to address inequality: C-TAP

- In May 2020, WHO launched C-TAP , the Covid-19 Technology Access Pool, an initiative of Costa Rica with the support of 36 other countries.
- C-TAP called on vaccine developers to share vaccine know-how through pooling and voluntary licensing agreements in a pandemic.
- It especially asked that companies who had received public funding to develop COVID-19 related products deposit all their intellectual property, test data, processes, and safety information into C-TAP.
- But no major company with a WHO approved vaccine has agreed to share technology with C-TAP.
- Most governments are reluctant to make it compulsory to share such knowledge. There was some hope that Oxford University's vaccine, developed through public funding, would be made open source, but the rights are assigned exclusively to AstraZeneca, which has not been fully transparent about its pricing and other sub-licensing terms.

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Failure of current schemes to address inequality: WHO mRNA transfer hub

- In June 2021, WHO announced that it was working with a consortium of South African vaccine companies, universities, and the Africa Centres for Disease Control and Prevention to establish its first covid mRNA vaccine hub.
- The aim was to expand the capacity of low- and middle-income countries (LMICs) to produce COVID-19 vaccines and scale up manufacturing to increase global access to these critical tools to bring the pandemic under control.
- The technology used was to either free of intellectual property constraints in LMICs, or that such rights are made available through non-exclusive licenses to produce, export and distribute the COVID-19 vaccine in LMICs, including through the COVAX facility.
- However, Pfizer and Moderna (the two manufacturers of mRNA vaccines) have so far declined requests to enter into voluntary licensing agreements with low and middle-income countries.

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The underlying problem: TRIPS, IP and patents rights

- The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement was negotiated at the World Trade Organization (WTO) from 1986 to 1994 and came into effect in January 1995.
- Prior to TRIPS, many developing countries provided no patent protection on pharmaceutical products (Brazil) or they recognised patents on process but not products (India).
- Some developing countries had patent coverage as short as three years (Thailand) or as long as sixteen years (South Africa).
- This flexibility on patent laws facilitated the local production of cheap generic medicines long before patents had expired in developed countries.

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The underlying problem: TRIPS, IP and patents rights

- Developed countries with a research based pharmaceutical industry, particularly the USA, used the TRIPS Agreement to remove the flexibility previously given to Member States.
- TRIPS required all countries, both developed and developing, to grant patent protection for pharmaceutical products and processes for 20 years (although developing countries were given longer periods in which to implement these changes).

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The underlying problem: TRIPS, IP and patents rights

- Without patent protection it would not be in the interests of the pharmaceutical industry to invest the large amount of money needed for the research and development of new drugs.
- However, if patents were held in perpetuity there would be no price competition from generic manufacturers and essential medicines might be affordable only by the rich.
- Thus, there is a tension between the need of the pharmaceutical innovator for intellectual property protection and the need of society for equitable and affordable access to innovative drugs, especially in a pandemic.

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Patented versus generic drugs

$2.15 **$15.99**

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Australian medicines policy: equitable access

- Limited list of cost-effective, necessary drugs.
- Cost subsidised by national or private insurance schemes.
- Prices negotiated using:
  - Pharmacoeconomic analysis (pay only what the drug is worth)
  - Monopsony buying power (counters monopoly power of pharmaceutical companies during patent protection)
  - Reference pricing (subsidise only the lowest price product in a generic group and in some therapeutic classes)
  - Generic substitution by pharmacists for drugs of proven therapeutic equivalence .

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Generic medicine promotion

https://www.youtube.com/watch?v=02WGtdzOznE

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The underlying problem: TRIPS, IP and patents rights

- Health activists and NGOs began a campaign to reassert the supremacy of public health needs over trade interests (TRIPS).
- This culminated in the 4th World Trade Organization (WTO) ministerial conference in Doha in November 2001.
- Led by the Africa Group, Brazil and India, a coalition of more than 80 developing countries convinced the major industrialized countries to affirm the Doha, "*Declaration on the Agreement and Public Health*" which stated that the 1995 TRIPS agreement,

  "can and should be interpreted and implemented to protect public health and promote universal access to medicines" (World Trade Organization, 2001).

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The underlying problem: TRIPS, IP and patents rights

- The response of U.S. (and some global pharma companies) has been to challenge the implementation of the Doha declaration and negotiate bilateral trade agreements containing IP standards much stronger than those to be found in TRIPS (e.g., US-AUST Free Trade Agreement).
- They have also used the courts to challenge attempts by countries to use compulsory licensing provisions of the Doha agreement.
- In 1998, a group of pharmaceutical companies brought a legal case against the South African government to stop it introducing laws aimed at making HIV and AIDS more affordable. The main objection was that such laws would weaken patent protection.
- The dispute sparked controversy worldwide and enhanced public awareness of the (sometimes) negative impact of intellectual property rights on human health. The companies eventually abandoned the case.

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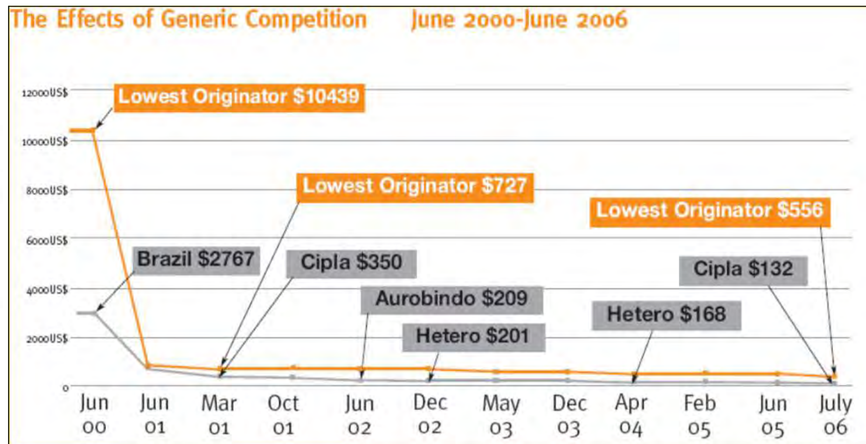
Removing patent protection: AIDS



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Waiving patent protection: Covid-19

- The governments of India and South Africa are leading a proposal to temporarily waive intellectual property protection on Covid-19 technologies, backed by over 100 countries.
- But vaccine manufacturers and many rich countries have blocked waiver discussions at the World Trade Organization (WTO).
- In May, Pfizer warned Australia against joining a growing push to waive the intellectual property protections for Covid-19 vaccines, arguing it could actually harm vaccine supply and invite unsafe copycats.
- In July, Department of Foreign Affairs and Trade officials told a Senate estimates hearing that Australia viewed the terms of the proposed waiver as too broad.
- In March, Minister for Trade, Dan Tehan explained Australia's hesitancy towards the waiver as being "to make sure that there are some protections in place for the millions of dollars that has gone into the research to create these vaccines".

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Waiving patent protection: Covid-19

- The United States, home to some of the world's biggest pharmaceutical companies, also blocked the waiver.
- But in May 2021, President Joe Biden backed it, albeit limited to vaccines.
- In September, the Australian Trade Minister Dan Tehan, cited a shift in US policy as the reason that Australia would change its mind.
- But the WTO's consensus-based voting system, still allows a minority of wealthy nations to block the waiver, currently including the European Union.
- So, unless Australia gets fully behind the TRIPS waiver in the negotiations climaxing in October, it mightn't get up.

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Discussion: Should Australia support the Covid-19 technology waiver?

Hon Dan Tehan MP
Minister for Trade, Tourism and Investment
dan.tehan.mp@aph.gov.au

- According to Medicines Australia and AusBiotech, patents are not the cause of the global problem which has seen just one per cent of the population in low-income countries receive at least one dose of a COVID-19 vaccine.
- "The proposed patent waiver is a wishful solution to a complex problem," de Somer and Chiroiu from Medicines Australia said.
- "Waiving patents for COVID-19 vaccines and therapies will not address the real challenges to vaccinating the world: eliminating trade barriers, addressing bottlenecks in supply chains, and a greater willingness to share more doses with developing countries".
- What do you think?
- And what action could you take?

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Is progress possible: Salk polio vaccine

- In 1955, Jonas Salk announced the development of a polio vaccine in the midst of a huge epidemic. The news was initially met with scepticism.
- When a huge placebo–controlled clinical trial involving 1.6 million children proved him right, he declared that in order to maximise the global distribution of this lifesaving vaccine his lab would not patent it. Asked who owned the patent, he famously replied:
  - 'Well, the people I would say. There is no patent. Could you patent the sun?'

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Covid-19 vaccine passports?

Australian Government

COVID-19 digital certificate

This individual has received all required COVID-19 vaccines.

Name	Date of birth
KEN J HARVEY	26 Jun 1944

Individual Healthcare Identifier (IHI)	Document number
8003 6010 2406 7576	100000766336

Valid from
01 Jul 2021

Vaccinations	Dates received
COVID-19 Vaccine AstraZeneca	15 Apr 2021, 01 Jul 2021

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Covid-19 vaccine passports?

Issues:

- Vaccine risks and benefits.
- Rising incidence of infection and death with delta variant.
- Hospital and ICU admissions increasing.
- Can test, trace, isolate and quarantine (TTIQ) measures be maintained?
- Can masks, social distancing, ventilation, and lockdowns be maintained?
- What about Australian vaccine inequality?
- Should employers, State or Commonwealth impose vaccine & testing mandates?

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Australian Covid-19 vaccines

	AstraZeneca	Pfizer	Moderna	Novavax (not yet)
Type	Adeno virus vector	mRNA	mRNA	Sub-unit protein
Doses	2, 4-12 weeks apart	2, 21 days apart	2, 28 days apart	2, 21 days apart
Effectiveness	All appear equally effective in preventing death and severe disease. Virus load and transmission may be reduced. But immunity wanes with time. Covid-19 variant breakthrough infection can occur.			
Side effects: mild	Injection site pain, fatigue, headache, muscle pain, chills, joint pain, fever, nausea, feeling unwell and swollen lymph nodes			Similar but may be less frequent
Side effects: severe	Thrombosis (TTS) 1 to 2 per 100,000 Fatalities around 0.5 to 1 per million	Myocarditis and pericarditis Females around 16 per million Males around 37 per million		None to-date
Storage	Normal fridge (2°C to 8°C	Domestic freezer temperatures (-25°C to -15°C) for up to 2 weeks		Normal fridge (2°C to 8°C
Cost	$4	$31	$41	$22

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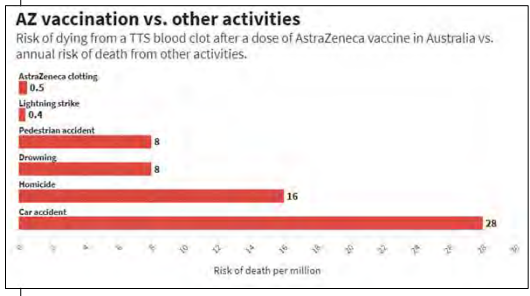
Putting risk in perspective

- Unvaccinated Americans have died at 11 times the rate of those fully vaccinated since the delta variant became the dominant strain.
- Vaccinated people were 10 times less likely to be admitted to hospital and five times less likely to be infected than unvaccinated people.
- However, vaccine efficacy has declined since the delta variant became dominant around mid-year. The decline in efficacy against hospital admission or death was small, but the protection offered against infection has slipped more significantly.
- The decline in vaccine efficacy was greatest in the over-65 age group, the study found. This might reflect declining immunity in people who were vaccinated early.



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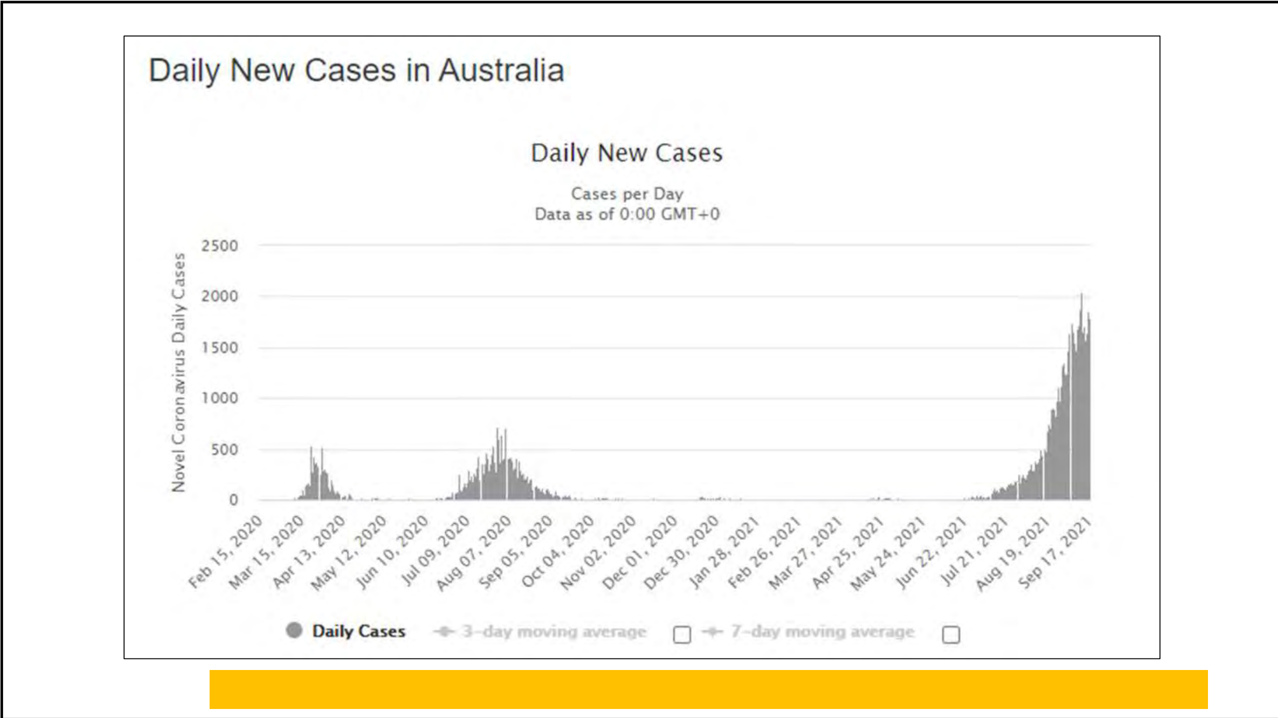

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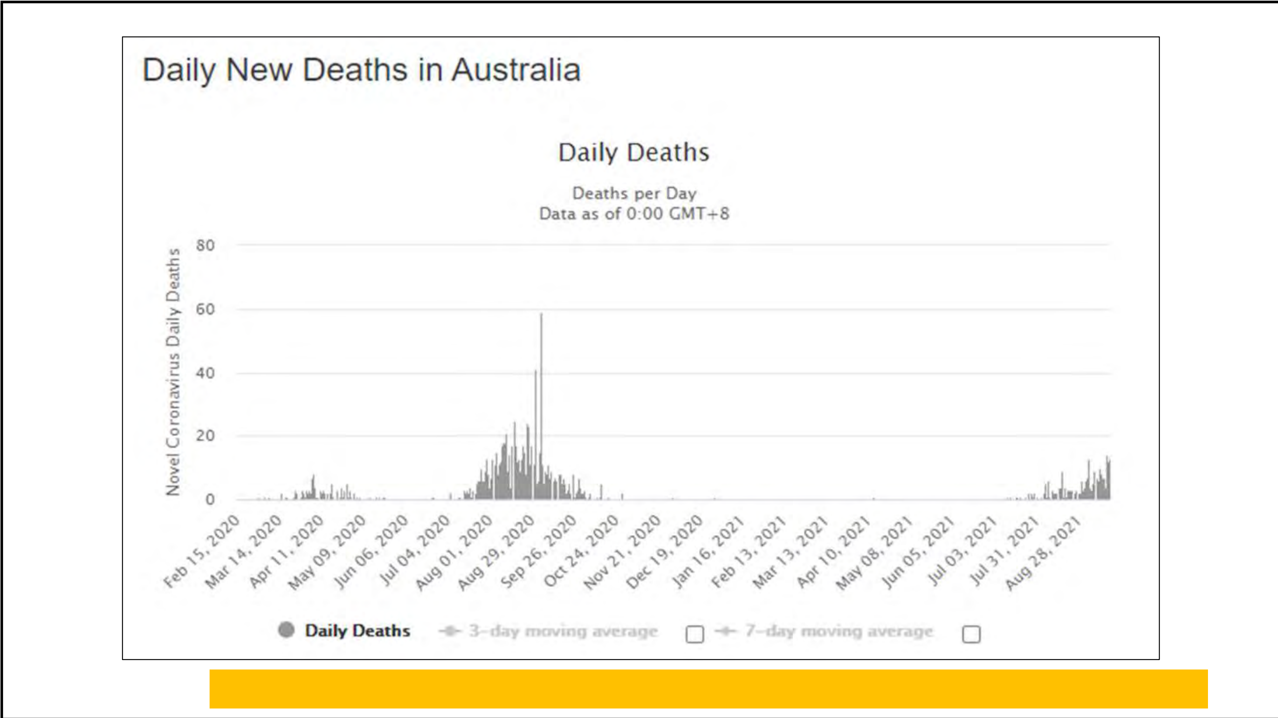

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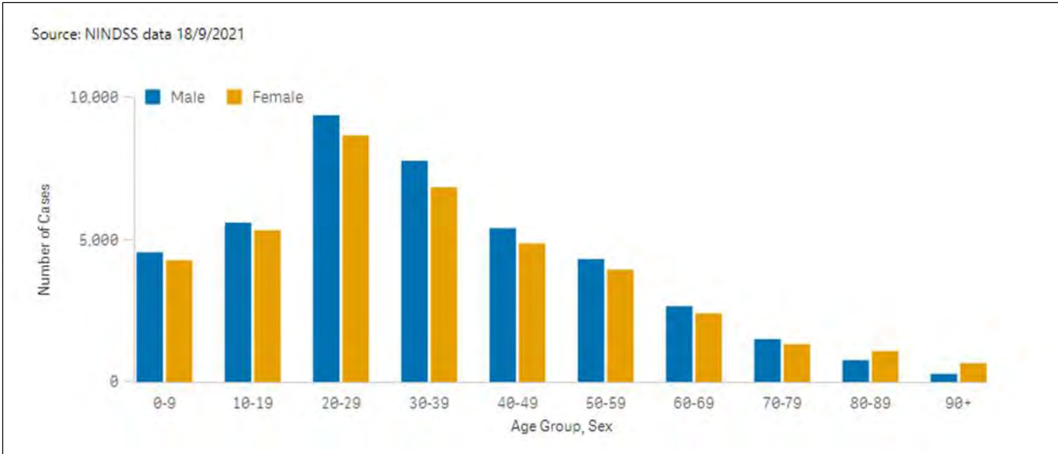
Australian COVID-19 cases by age group and sex



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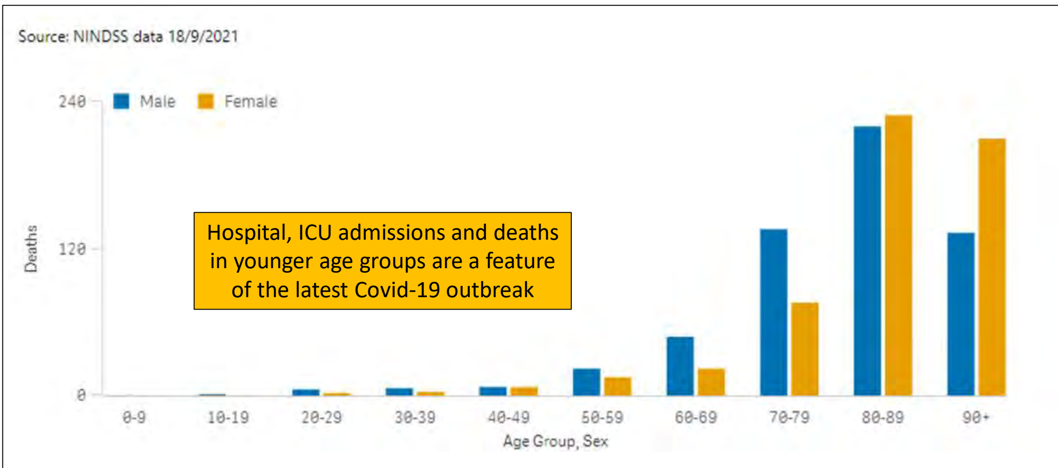
Australian COVID-19 deaths by age group and sex



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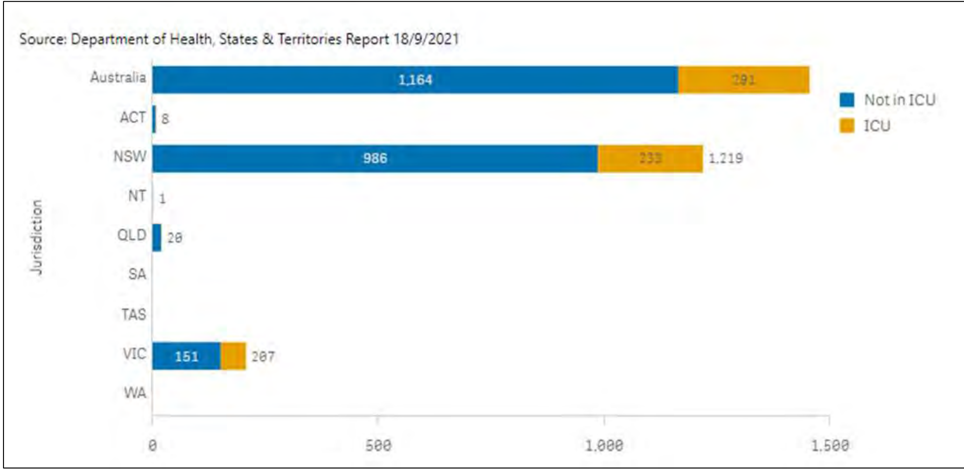
Current COVID-19 cases in hospitals and Intensive Care Units (ICUs)



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Masks, social distancing, ventilation, isolation, lockdowns

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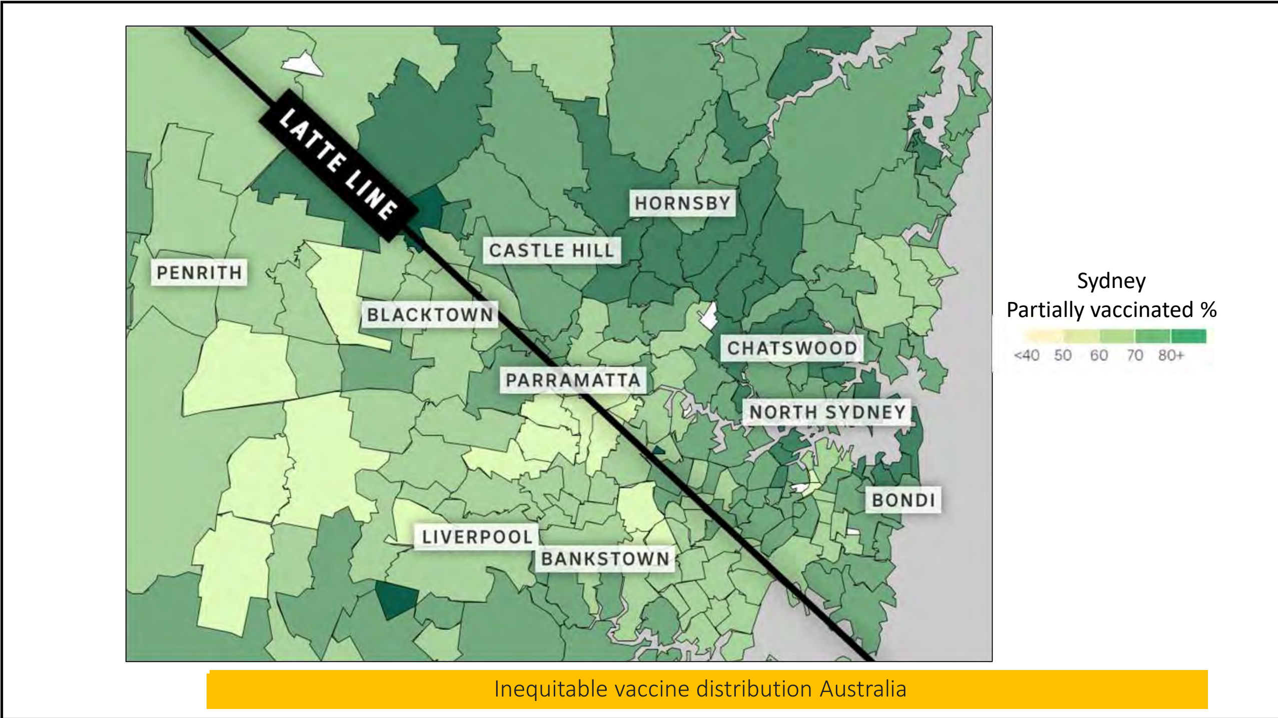

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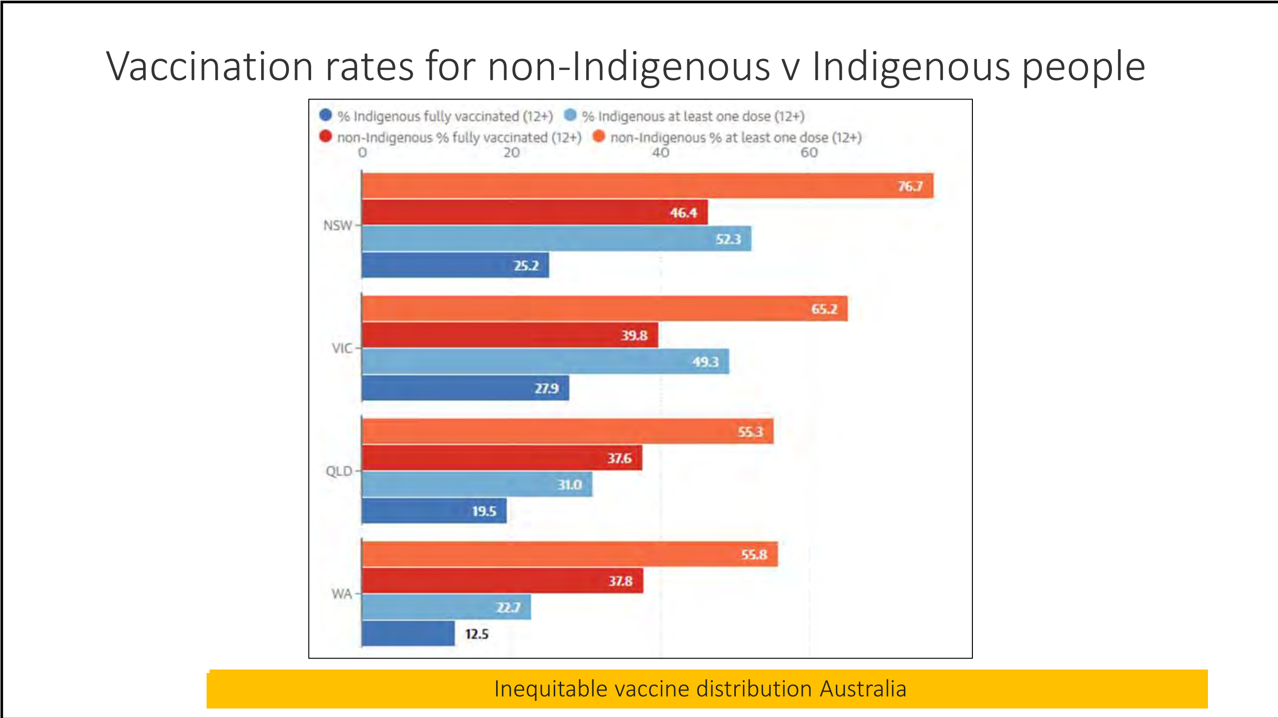

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Vaccine passports: pro and con

- Pros
  - Freedoms offered, such as travel, pubs and restaurants, may motivate people to get vaccinated.
  - They will increase employment opportunities for those employers that mandate them.
  - If vaccines significantly reduce the chance of becoming seriously ill in a pandemic, there can be a justification for using coercion to employ them to protect the health system and others in a public health emergency. But we don't issue non-smoking or non-obese certificates.
- Cons
  - Vaccination for COVID in low-risk groups such as children and young people is less clearly in their interests, though it is in the interests of older people.
  - Discrimination - passports will be used to give people who are vaccinated and presumed to have immunity the ability to do things that others cannot. Given that the vaccine rollout is based on a priority system, some people will be vaccinated before others through no fault of their own.
  - Administrative failures that have plagued every aspect of Australia's response. For example, security flaws enabling certificates to be forged, and incomplete records stopping certificate downloads.

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Vaccine passports: pro and con

- The libertarian/classical liberal answer is simple. Private owners have a right to who comes on to their property and who doesn't. You can't come in wearing thongs or without a vaccine passport.
- But those property rights have been limited by law repeatedly on grounds of discrimination on race, gender, religion, etc. So, on which side of that line does vaccination fall?
- And to what services does it apply? You can throw a drunk or someone in a swastika T-shirt out of your pharmacy, but can you refuse service to the unvaccinated?
- Do we need a strong, actively enforced, vaccine mandates requiring people to get vaccinated by a certain date(or test COVID-19 negative) before being allowed entry to flights, cinemas, pubs, restaurants, etc.? Or not?

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Discussion: Covid-19 vaccine passports?

- What do you think?

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Finally, on a lighter note…

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Further reading

- Hassan F, Yamey G, Abbasi K. Profiteering from vaccine inequity: a crime against humanity? BMJ 2021; 374: n2027 doi:10.1136/bmj.n2027. https://www.bmj.com/content/bmj/374/bmj.n2027.full.pdf
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